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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/530,832 | 11/03/2005 | Gaetan Terrassse | N/A | 2502 |

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| EXAMINER | |
|---|---|
| NGUYEN, HUONG Q | |
| ART UNIT | PAPER NUMBER |
| 3736 | |

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/530,832 | TERRASSSE ET AL. | |
| | Examiner | Art Unit | |
| | Helen Nguyen | 3736 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Specification*

1. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

**Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. *Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading.* If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

### *Claim Objections*

2. **Claim 1** is objected to because of the following informalities:

The phrase "in plane" should be modified to grammatically correctly express applicant's desired structure.

Examiner also respectfully requests that applicants reexamine Claims 1-20 and make the necessary correction regarding grammar or syntax.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. **Claims 1-2, 4, 10-12, and 16-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldo et al (US Pat No. 5099857) in view of Maganias (US Pat No. 4802493).

5. In regards to **Claim 1**, Baldo et al disclose a cutaneous diagnostic kit for patient's atopy applied by a doctor or a nurse comprising:

a central cylindrical body, best seen in Figure 2, wherein an upper face is bonded to a single body of gripping and pressure (7'), also best seen in Figure 2 (Col.4, line 5-9, 38).

Baldo et al also disclose another embodiment wherein a cavity (5) with an allergen composition (1) (Col.4, line 61-63), best seen in Figure 4, supports a multi-point needle, best seen in Figure 6C (Col.5, line 14-15).

6. Because Baldo et al disclose both a central body with a body for gripping as well as a cavity that supports a multi-point needle, it would have been obvious to one of ordinary skill in the art to combine the two embodiments such that said central body bonded to a body for gripping includes a cavity coaxial of said central body being of such height such that its lower end goes beyond the bottom edge of said central body and supports a multi-point needle to create an enhanced device.

7. Furthermore, Baldo et al disclose in another embodiment a central body being bonded on all its circumference with the inner edge of a flexible ring found within "top covering layer" (14) (Col.5, line 22-26), the outer edge of the aforementioned flexible ring being bonded on all its circumference to a rigid support defined as all the layers placed below said ring, as best seen in Figure 10. Therefore, it would have been obvious to incorporate the concept of said ring with the combined embodiments described above to create a superior device as reasoned above.

8. Additionally, Baldo et al disclose a blister, referred to as "bottom layer"(9), fixed on the lower face of the support and covering the totality of the lower surface of the kit (Col.4, line 13-15).

9. Baldo et al also disclose an embodiment illustrated in Figure 10 wherein allergen composition (1) is located at the lower face of said flexible ring (14). Once again, it would have been obvious to one of ordinary skill in the art to combine this teaching with the combination of embodiments described above such that allergen composition is not only located within said

cavity (5) but also beneath the lower face of said flexible ring, thus existing between said blister (9) and the lower face of said flexible ring.

10. However, Baldo et al do not disclose the lower face of said central body having an acute edge. Maganias discloses a skin allergy device comprising a central body (18') having an acute edge, as best seen in Figure 3, which is then connected to a multi-point needle (16') as an optimal design for use as well as proper retaining of allergen composition (Col.4, line 5-7). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Baldo et al described above to such that said central body includes an acute edge, as taught by Maganias, for optimal retaining of the cavity containing said allergen composition as well as an optimal design for enhanced performance.

11. In regards to **Claim 2**, Baldo et al disclose said cutaneous diagnostic kit for patient's atopy applied by a doctor or a nurse comprising three central bodies, as best seen in Figure 7.

12. In regards to **Claim 4**, Baldo et al disclose said cutaneous diagnostic kit for patient's atopy applied by a doctor or a nurse, wherein the distance designated as reference number (9) in applicant's Figure 6 is between 1 centimeter and 3 centimeters, the distance designated as reference number (10) in applicant's Figure 6 is between 2 centimeters and 4 centimeters, and the distance designated as reference number (11) in applicant's Figure 6 is between 3 and 7 centimeters, wherein Baldo et al disclose a minimum of 20 mm (2 cm) between separate units (Col.2, line 61-63) such with such a minimum distance, the distance designated as reference number (11) in applicant's Figure 6 is approximately 4 cm.

13. In regards to **Claim 10**, Baldo et al disclose said cutaneous diagnostic kit for patient's atopy applied by a doctor or a nurse wherein said allergen composition can be in the form of gel, of liquid, emulsion or suspension (Col.2, line 64-66).

14. In regard to **Claims 11-12 and 16-18**, Baldo et al disclose said cutaneous diagnostic kit for patient's atopy applied by a doctor or a nurse but are silent as to the specific composition of said allergens. Maganias discloses a skin allergy testing device for testing any allergen such as but not limited to common allergens such as graminaceous, herbaceous and trees pollens as well as domestic environmental allergens such as those relating to cats and dogs, as well as molds (Col.3, line 6-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the diagnostic kit of Baldo et al to specify the allergen for testing as graminaceous, herbaceous, and trees pollens as well as those relating to cats, dogs, and mold, as taught by Maganias, to determine common allergies. Moreover, although Baldo et al in combination with Maganias do not specify specific domestic allergens for testing, it is obvious to one of ordinary skill within the art that specifically identified allergens may be tested, and that any of such allergens are may be tested, such that it would be obvious to one of ordinary skill within the art to test allergens such as tropomyosines, profilines, and cystine proteases.

15. In regards to **Claim 19**, Baldo et al disclose said cutaneous diagnostic kit for patient's atopy applied by a doctor or a nurse wherein each one of the said central bodies contains an allergen composition different from that of the other central bodies (Col.2, line 49-58).

16. In regards to **Claim 20**, Baldo et al disclose said cutaneous diagnostic kit for patient's atopy applied by a doctor or a nurse consisting of materials of single use.

17. **Claims 3, 6, and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldo et al in view of Maganias, further in view of Fishman et al (US Pat No. 5139029).

18. In regards to **Claim 3**, Baldo et al in combination with Maganias disclose a cutaneous diagnostic kit for patient's atopy applied by a doctor or a nurse but do not disclose the distance designated as reference number (9) in applicant's Figure 6 is different from the distance designated as reference number (10) in applicant's Figure 6, both of the two distances different from the distance designated as reference number (11) in applicant's Figure 6. Fishman et al disclose a skin allergy testing device wherein it is advantageous to have unequal spacing between needle piercing points to effectively mark the placement of allergens tested (Col.6, line 47-59). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Baldo et al as modified by Maganias such that the distances described above are all different, as taught by Fishman et al, to allow effective marking of test sites.

19. In regard to **Claim 6**, Baldo et al in combination with Maganias disclose said cutaneous diagnostic kit for patient's atopy applied by a doctor or a nurse with a multi-points needle but do not disclose said needle in the form of a crown on which are positioned the points. Fishman et al disclose a skin allergy testing device using crown type needles having a plurality of extending

needles for effective intradermal testing (Col.13, line 10-20, 46-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the multi-points needle of Baldo et al as modified by Maganias to be in the form of a crown on which needle points are positioned, as taught by Fishman et al, to enable effective intradermal testing.

20. In regards to **Claim 14**, Baldo et al in combination with Maganias disclose said cutaneous diagnostic kit for patient's atopy but do not disclose said allergen composition includes a mixture of food allergens. Fishman et al teach that is beneficial to test for common allergies such as food allergies (Col.1, line 25-26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Baldo et al as modified by Maganias such that said allergen composition includes a mixture of food allergens to test for common food allergies and improve said testing device.

21. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldo et al in view of Maganias, further in view of Zeytinoglu et al (US Pat No. 5874226). Baldo et al in combination with Maganias disclose said cutaneous diagnostic kit but are silent as to the dimensions of said cavity. Zeytinoglu et al disclose a skin testing device comprising a cavity, referred to as "retainer" (1), that is preferably 0.5 cm high to enable proper containment of test agents, best seen in Figure 1 (Col.3, line 1-4, 46). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Baldo et

al as modified by Maganias such that said cavity has a height ranging between 0.2 centimeter and 1 centimeter for optimal containment of test agents and functioning.

22. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldo et al in view of Maganias, further in view of Fishman et al, further in view of Pitesky (US Pat No. 6258041). Baldo et al in combination with Maganias and Fishman et al disclose said cutaneous diagnostic kit comprising a multi-points needle situated on a crown but do not disclose said needle with eight points. Pitesky discloses an allergy testing device using a needle with preferably eight points, referred to as "tines" (32) (Col.4, line 52-56), best seen in Figure 8, for the most satisfactory test results (Col.10, line 7-11). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the multi-point needle crown of Baldo et al as modified by Maganias and Fishman et al, to contain eight points, as taught by Pitesky, for optimal testing results.

23. **Claims 7 and 9** are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldo et al in view of Maganias, further in view of Fishman et al, further in view of Pitesky, even further in view of Trautman et al (US Pat No. 6083196). Baldo in combination with Maganias, Fishman et al, and Pitesky disclose said cutaneous diagnostic kit described above but do not disclose several concentric crowns, each comprising four points positioned thereon. Trautman et al disclose a transdermal device comprising of needle points, referred to as "microprotrusions" (4), arranged on at least two concentric crowns such that said configuration enables sufficient area for agent holding, best seen in Figure 7 (Col.7, line 42-50). Therefore, it would have been

obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Baldo et al as modified by Maganias, Fishman et al, and Pitesky such that said needle comprises four points arranged on two concentric crowns, as taught by Trautman et al, to increase effective agent holding during use of the device.

24. **Claim 13** is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldo et al in view of Maganias, further in view of Holm et al (US Pub No. 20030175312), Palacios Pelaez et al (WO 98/59052), and Vogel et al (US Pat No. 6864404). Baldo et al in combination with Maganias disclose said cutaneous diagnostic kit for patient's atopy testing pollens allergens but do not specify the type of pollen allergen. Holm et al teach that PR-10 proteins may be possible allergens (¶0392), Palacios Pelaez disclose profiline as a plant allergen (abst), and Vogel et al disclose that pectate lyase are also possible human allergens (Col.1, line 51-52). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Baldo et al as modified by Maganias such that PR10, profilines, and pectate lyase, as taught by Holm et al, Palacios Pelaez et al, and Vogel et al respectively, are tested for as possible allergens.

25. **Claim 15** is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldo et al in view of Maganias, further in view of Fishman et al, even further in view of Lusk et al (US Pat No. 6423546). Baldo et al in combination with Maganias and Fishman et al disclose said cutaneous diagnostic kit for patient's atopy for testing food allergens but do not identify specific allergens to be tested. For example, Lusk et al teach that lipid transfer proteins as potential food allergens (Col.8, line 13-14) and should be tested on individuals. Therefore, it would have been

obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Baldo et al as modified by Maganias and Fishman et al to include testing of specific food allergens, such as lipid transfer proteins, as taught by Lusk et al, as well as any other specific allergens including chitinases, as possible allergens during device use.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HQN

8/7/2006

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